

REMARKS

The foregoing amendment and remarks which follow are responsive to the Final Office Action mailed January 23, 2006 in relation to the above-identified patent application, and is being submitted in connection with Applicants' Request for Continued Examination.

In that Office Action, Claims 39-42 and 45-48 were withdrawn from consideration as allegedly being directed to a non-elected invention. Claim 43 was further objected to as allegedly including material which was not supported by the original disclosure. With respect to the prior art, Claims 19, 20, 35, 43 and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Seitzinger (i.e., United States Patent Number 5,362,294), in view of Buncke (i.e., United States Patent Number 5,931,855), and further in view of Towfigh (i.e., DE 32 27 984 A1). No other issues were presented.

In order to overcome the stated grounds for rejecting the claims, as well as to place the claims in condition for allowance, the Applicants have amended the claims to more precisely identify the novel and non-obvious aspects thereof. Specifically, Applicant has amended dependent Claim 19 to recite a surgical tissue implant including **a sling that remains permanently implanted within a patient** that is disposed upon an end of at least one suture having a plurality of anchor members disposed linearly thereupon and operative to penetrate into and become imbedded within soft tissue at a selected target sight **such that the sling remains in permanent orientation relative the internal organ or tissue that the sling is adjacent.**

Similarly, Applicant has further amended independent Claim 35, directed to a method for providing **permanent** support to an internal organ or tissue that recites the step of providing an implant having a sling disposed between the proximal ends or first and second suture lines, the latter having a plurality of anchor mechanisms disposed linearly thereupon, respectively, where each one of the anchor members is operative to penetrate into and become embedded **(fixed in position)** within the target sight of soft tissue, and introducing such implant within a patient's body **such that the sling is permanently positioned adjacent to said internal organ or tissue** and the suture lines advanced through dedicated target sights of soft tissue and **become imbedded within soft tissue at said target sights**

such that the sling is maintained in a fixed position and orientation relative the internal organ or tissue.

As amended, independent Claims 19 and 35 are clearly novel and non-obvious over the prior art. Indeed, not only do the prior art references fail to teach or suggest the present invention as claimed, such references actually teach away from the claimed invention. Indeed, if these references were somehow modified to derive the present invention, would render at least the primary reference, namely, Seitzinger, completely inoperable for its intended purpose. In this regard, it should be appreciated that the present invention is directed to surgical implants and methods of providing support to organs and tissue that provide for **a sling that is permanently implanted in fixed position** relative an organ or tissue to thus provide permanent post-operative support to such anatomical structures. See, e.g., page 11, lines 8-19; page 25, lines 4-11. Indeed, implants of the present invention are particularly intended for use in providing long-term urethral support for the treatment of incontinence. See Application, page 23, lines 23-32; page 24, lines 16-20; Figure 16 and 16a.

The Seitzinger reference, in contrast, discloses a sling for retracting a body organ during a laparoscopic surgical operation. Such sling is neither intended nor adapted to ever be used as a permanent surgical attachment, but rather is to be **removed from the body following the laparoscopic surgical procedure**. See, column 2, lines 4-8 (“when the operation is complete ... the sling [is] removed from the organ which returns to its normal position. The sling is next withdrawn through the cannula ...”; column 3, lines 26-29; and Abstract. Accordingly, the Seitzinger reference is limited exclusively to **temporary use** of slings that are to be **deployed only during laparoscopic procedures** and are not to be permanently implanted.

However, with respect to the use of the slings disclosed in Seitzinger, such slings are meant to retract a body organ so that it does not interfere with the surgical procedure. Column 1, lines 30-32 and 50-53; Column 2, lines 20-22; Abstract. Sutures on opposed ends of the sling extend through the patient’s abdominal wall and clamped **outside of the body**. Column 3, lines 7-20; Figure 3 (note specific reference to clamp 26). Indeed, such teachings enable the surgeon to “easily change the position” of the organ during the surgical procedure. Column 3, lines 18-20.

The ability to easily change the position of an organ during surgery could not be accomplished by using the one-way sutures and anchors of Buncke and Towfig. As will be easily appreciated, Buncke and Towfig teach uni-directional suture and anchoring devices and, if used with the slings disclosed in Seitzinger, could only be used to raise or lift an organ and would **not** enable the surgeon to “easily change the position” of the organ as is taught by the Seitzinger reference. Indeed, even assuming for sake of argument that the one-way suture and anchor of Buncke and Towfig were used with the sling of Seitzinger, to the extent a surgeon were to pull too much on the sling via such sutures and anchors, the surgeon would have no alternative but to cut the suture with anchors from the sling, pull the cut suture from the body, laparoscopically introduce another one-way suture with anchors, tie the same to the sling, and again advance such suture with anchors through the abdominal wall to “try again.”

As should be appreciated, prior art references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02 VI. In this case, when taken as a whole, it is clear that the cited references are incompatible with one another and do not teach or suggest Applicants’ invention.

Moreover, even assuming that the aforementioned references could be combined or modified does not render the combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990); MPEP § 2143.01 III. It is likewise particularly inappropriate to combine references where the references teach away from their combination. In re Grasselli, 713 F2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983); MPEP § 2145. It is further well understood that any proposed modification that would render the prior art inoperable for its intended purpose is inappropriate in maintaining an obviousness rejection. In re Gordon, 733 F2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); MPEP § 2143.01 V.

Applicants respectfully submit that each of the foregoing bases applies with respect to the rejection being maintained in the Office Action and, in light of the amendments being made to the claims herein, any rejection maintained under 35 U.S.C. § 103(a) in view of the combination of the Seitzinger, Buncke and Towfig references, either alone or in combination,

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cannot properly be maintained. Applicants therefore respectfully request that such rejection be withdrawn.

In addition to the foregoing, Applicants have further amended the claims in accordance with the Office Action of January 23, 2006. Specifically, Applicant has withdrawn Claims 39-42 and 45-48 from consideration and has further cancelled Claim 43. Applicant has further added new Claims 49-52, of which Claim 49 depends from independent Claim 19 and Claims 50-52 depend from Claim 35, and are directed respectively to types of materials for forming the sling component (Claim 49) and methods involving the placement of a sling at or near the urethra (Claims 50-52). Such claims are fully supported in the specification page 23, line 23 to page 25, line 29 and Figures 16, 16a, and thus do not introduce new matter. Such claims are likewise believed to be within the scope of the elected invention.

Based on the foregoing, Applicant respectfully submits that the claims, as amended herein, are now in condition for immediate allowance. Early notice to that effect is respectfully requested. To the extent the Examiner has any questions, requires additional information, or has any suggestions to resolve any outstanding issues that may exist, the Examiner is invited to contact Applicant's counsel at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 7/21/06

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